1. The drawings are objected to because in Figure 3, the word "Photocoagulation" is misspelled in the y-axis labels of both graphs. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

The claim for priority at page 1, lines 8-9, of the specification does not recite a serial number for the parent provisional application.

3. Claims 5 and 10 are objected to because of the following informalities: At claim 5, line 2, the comma after "or" should be deleted. At claim 10, line 1, "is" should be changed to "are". Appropriate correction is required.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35-39 of copending Application No. 10/175,833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '833 application anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In

addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by the McCombe et al article (Eye, Vol. 5, pages 569-575). The McCombe et al article teaches treating diabetic retinopathy by administering a somatostatin analog, BIM23014. The patients either improved or did not demonstrate any further deterioration. See, e.g., the Abstract.

6. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the McCombe et al article (Eye, Vol. 5, pages 569-575) as applied against claims 1 and 2 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-2817). The McCombe et al article teaches using a somatostatin analog having high binding activity, but does not teach first characterizing the binding activity of the somatostatin analog to the sstr2 receptor before its use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including BIM 23014, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the BIM23014 of the McCombe et al article to the sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the results of such an assay would not affect the teaching of the McCombe et al article that BIM23014 is actually useful in the treatment or prevention of diabetic retinopathy.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by the Kirkegaard et al article (Acta Endocrinologica, Vol. 122, pages 766-772). The Kirkegaard et al article teaches treating diabetic retinopathy by administering octreotide. See, e.g., the Abstract. For one patient, the morphology improved from Grade III to Grade I during the course of the study (see page 768, column 2, lines 25-28), and accordingly Applicant's claims are anticipated. Alternatively, because the same active agent is being administered to the same patients by the same method steps, inherently diabetic retinopathy will be treated or prevented in the method of the Kirkegaard et al article to the same extent claimed by Applicant.

8. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over the Kirkegaard et al article (Acta Endocrinologica, Vol. 122, pages 766-772) as applied against claims 1 and 2 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-2817). The Kirkegaard et al article teaches using a somatostatin analog, but does not teach first characterizing the binding activity of the somatostatin analog to the sstr2 receptor before its use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including octreotide/SMS 201-995, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the octreotide of the Kirkegaard et al article to the sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the results of such an assay would not affect the

teaching of the Kirkegaard et al article that octreotide was actually useful in the treatment or prevention of diabetic retinopathy in one patient.

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Bodor et al (U.S. Patent No. 6,440,933). Bodor et al teach treating diabetic retinopathy by administering somatostatin analogs, e.g., lanreotide, octreotide, or conjugates of these compounds for retinal delivery. See, e.g., column 4, lines 22-37; column 4, line 47 - column 5, line 10; column 5, lines 37-48; column 15, lines 9-19; and column 26, lines 1-10.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Bodor et al (U.S. Patent No. 6,440,933) as applied against claims 1 and 2 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-2817). Bodor et al teach using somatostatin analogs, but do not teach first characterizing the binding activity of the somatostatin analogs to the sstr2 receptor before their use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including lanreotide and octreotide, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the somatostatin analogs of Bodor et al to the sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the results of such an assay would not affect the teaching of Bodor et al that lanreotide, octreotide, and conjugates of these compounds are actually useful in the treatment or prevention of diabetic retinopathy.

11. Claims 1-6, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). The Grant et al abstract teaches treating diabetic retinopathy by administering a combination of octreotide and 100-200 μg/day thyroid hormone/levothyroxine.

12. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156). Application of the Grant et al abstract is the same as in the above rejection of claims 1-6, 17, and 18. The Grant et al abstract does not teach it active agents in kit form in syringes or oral dosage forms, and does not teach optimizing the relative dosages of the active agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al abstract in kit form because it is routine in the pharmaceutical arts to provide active agents in kit form for ease of storage, transportation, measurement, and administration. It would further have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the active agents of the Grant et al abstract in the form of syringes or in oral dosage forms because these are conventional forms for administering pharmaceutical agents. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal dosages and relative dosages for the active agents of the Grant et al abstract because dosage is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

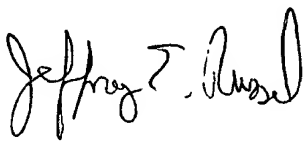
13. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being obvious over the Grant et al abstract (Diabetes, Vol. 48, Suppl. 1, pages A155-A156) as applied against claims 1-6, 17, and 18 above, and further in view of the Patel et al article (Endocrinology, Vol. 135, pages 2814-

2817). The Grant et al abstract teaches using octreotide, but do not teach first characterizing the binding activity of the octreotide to the sstr2 receptor before their use. The Patel et al article teaches that it is known to characterize the binding activity of various somatostatin analogs, including octreotide, to various somatostatin receptors, including SSTR2 (see, e.g., Table 1). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to further characterize the binding activity of the octreotide of the Grant et al abstract to the sstr2 receptor, because the Patel et al article shows that this is a property of interest for the clinical use of somatostatin analogs, because it is routine in the pharmaceutical arts to characterize the chemical and physiological properties of therapeutic agents, and because the results of such an assay would not affect the teaching of the Grant et al abstract that octreotide is actually useful in the treatment or prevention of diabetic retinopathy.

14. The reference crossed off on the Information Disclosure Statement was crossed off because the examiner could not locate a copy of the reference in the file. Applicant is requested to re-supply a copy of the reference, plus its publication date, so that the examiner can consider it and make it of record.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1653

JRussel

September 18, 2002